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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Carlton C. Bull
Owner, Herd Manager
Cha-Liz Farm, LLC
1032 Ashley Road.
West Chazy, New York 12992-3608

January 26, 2004

NYK-2004-04

Dear Mr. Bull:

On December 4 and 17, 2003, U.S. Food and Drug Administration investigators conducted an inspection at your farm located in West Chazy, New York. This inspection confirmed that on two occasions you offered animals for sale for food that were adulterated within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act, 21 U.S.C. §§ 342(a)(2)(C)(ii) and 342(a)(4). The inspection also revealed that you caused animal drugs to be unsafe under Section 512(a) of the Act, 21 U.S.C. §360b, and adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5), because the drugs were used in a manner that did not conform to their approved use or to the regulations for Extra-Label Drug Use in Animals, Title 21, Code of Federal Regulations (CFR), Part 530.

On or about April 10, 2003, you offered for sale a cow identified with back tag 13IM2798, ear tag 2016 for slaughter as human food. The cow was sold to and slaughtered at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 2.35 parts per million (ppm) and 1.59 ppm sulfadimethoxine in liver and muscle tissues, respectively.

On or about September 24, 2003, you offered for sale a cow identified with back tag 13IZ5159, ear tag 481 for slaughter as human food. The cow was sold to and slaughtered at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 0.10 ppm penicillin in kidney tissue.

A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in edible tissues of cattle. 21 CFR 556.640. A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissues of cattle. 21 CFR 556.510. The presence of these drugs in excess of the established tolerances in the tissues of these animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act, 21 U.S.C. § 342(a)(2)(C)(ii).

Our investigation also found that you hold animals on your farm under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system for assuring that drugs are used in a manner not contrary to label instructions, and for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. Foods from animals held under such conditions are adulterated under Section 402(a)(4) of the Act, 21 U.S.C. § 342(a)(4).

Moreover, your actions caused drugs to become adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5), when you used the drugs in an extra-label manner without veterinary supervision, failed to follow the withdrawal period indicated on the drugs' labeling prior to slaughter, and/or exceeded the dosage amount. Specifically, you caused the adulteration of sulfadimethoxine injection ([redacted] and penicillin G Procaine [redacted] because your extra-label use of the drugs was not in compliance with 21 CFR Part 530, and therefore, the drugs were unsafe to use under Section 512(a) of the Act, 21 U.S.C. §360b.

You should not consider this an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act. Likewise, the fact that you caused the adulteration of a drug that had been sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Laurence D. Daurio, Compliance Officer, at the above address.

Sincerely,

Jerome G. Woyshner
District Director